

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: *DE JONG et al.*  
Serial No.: 10/086,745  
Filed: February 28, 2002  
Confirmation No.: 8781  
For: *METHODS FOR DELIVERING  
NUCLEIC ACID MOLECULES INTO  
CELLS AND ASSESSMENT THEREOF*  
Art Unit: 1636  
Examiner: Unassigned

#70

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INFORMATION DISCLOSURE STATEMENT IN ACCORDANCE  
WITH 37 C.F.R. §§ 1.97-1.98

Commissioner for Patents  
U.S. Patent and Trademark Office  
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Arlington, VA 22202

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Dear Sir:

Since this Information Disclosure Statement is filed before the receipt of a first Office Action on the merits for the above-captioned application, no filing fee is due. If it is determined that a fee is due, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-1213.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all references known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. The Forms PTO-1449 (10 pages) are provided herewith in connection with the above-captioned application. The references listed on the Forms PTO-1449 marked with an asterisk are not provided herewith as they have been previously provided or cited by the Examiner in connection with U.S. Serial No. 09/815,981, which is relied upon for an earlier filing date in accordance with 35 U.S.C. §120.

**U.S.S.N. 10/086,745**  
**de Jong *et al.***  
**Information Disclosure Statement**

The documents listed on the Forms PTO-1449 and supplied herewith are in the English language. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

Applicant also makes known to the Examiner the following U.S. applications which are commonly owned and/or have one or more inventors in common.

<u>Serial No.</u>	<u>Filing Date</u>	<u>Docket No.</u>
91304160.4	05/09/91	24601-401EP
09/096,648	06/12/98	24601-402A
09/724,726	11/28/00	24601-402E
09/724,872	11/28/00	24601-402F
09/724,693	11/28/00	24601-402G
09/799,462	04/17/01	24601-402H
09/815,979	03/22/01	24601-402I
10/125,767	04/17/02	24601-402J
10/151,078	05/16/02	24601-402K
10/151,081	05/16/02	24601-402L
10/219,694	08/14/02	24601-402M
97920284.3	04/10/97	24601-402EP
09/815,979	03/22/01	24601-416
09/815,981	03/22/01	24601-416B
10/086,745	02/28/02	24601-416C
PCT/US02/09262	03/22/02	24601-416PC
10/161,408	05/30/02	24601-419
PCT/US02/17451	05/30/02	24601-419PC
10/161,403	05/30/02	24601-420
PCT/US02/17452	05/30/02	24601-420PC
60/377,547	05/01/02	24601-P426

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the references, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(h), the filing of this Information Disclosure Statement shall not be construed to mean that a

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**de Jong *et al.***  
**Information Disclosure Statement**

search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

Applicant respectfully requests that the Examiner review the foregoing reference and information and that they be made of record in the file history of the above-captioned application.

\* \* \*

Respectfully submitted,  
HELLER EHRMAN WHITE & McAULIFFE LLP

By:

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Stephanie L. Seidman  
Registration No. 33,779

**Dated: October 29, 2001**  
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Dear Sir:

Transmitted herewith are an Information Disclosure Statement, Forms PTO-1449 (10 pages) and cited references for filing in connection with the above-identified application.

- ( X ) The Commissioner is hereby authorized to charge any fees that may be due under 37 C.F.R. §§1.16-1.17 in connection with this paper or with this application during its entire pendency to Deposit Account No. 50-1213. A duplicate of this sheet is enclosed.

Respectfully submitted,  
HELLER EHRMAN WHITE & McAULIFFE LLP

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Stephanie L. Seidman  
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FORM PTO-1449 (Modified)	ATTY. DOCKET NO. 24601-416C	SERIAL NO. 10/086,745
	APPLICANT De Jong <i>et al.</i>	
	FILING DATE February 28, 2002	GROUP 1636

LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANT'S INFORMATION DISCLOSURE  
STATEMENT

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	Ref. No.	DOCUMENT NUMBER							DATE	NAME	CLASS	SUB CLASS	FILING DATE
*	A	4	8	9	7	3	5	5	01/30/90	Eppstein <i>et al.</i>	435	240.2	10/29/87
*	B	4	9	3	7	1	9	0	06/26/90	Palmenberg <i>et al.</i>	435	69.1	10/15/87
*	C	5	2	0	8	0	6	6	05/04/93	Fujisaki <i>et al.</i>	427	96	04/30/92
*	D	5	2	8	8	6	2	5	02/22/94	Hadlaczky	435	172.2	09/13/91
*	E	5	3	1	8	5	1	5	06/07/94	Wilk	604	30	08/17/92
*	F	5	3	3	4	7	6	1	08/02/94	Gebeyehu <i>et al.</i>	564	197	08/28/92
*	G	5	3	8	9	0	6	9	02/14/95	Weaver	604	21	09/17/93
*	H	5	5	0	1	6	6	2	03/26/96	Hofmann	604	20	09/12/94
*	I	5	5	0	7	7	2	4	04/16/96	Hofmann <i>et al.</i>	604	53	01/21/94
*	J	5	5	5	0	2	8	9	08/27/96	Eppstein <i>et al.</i>	564	293	04/03/95
*	K	5	6	7	6	1	5	1	10/14/97	Yock	128	662.06	12/03/93
*	L	5	6	9	5	9	6	7	12/09/97	Van Bokkelen <i>et al.</i>	435	91.1	06/07/95
*	M	5	7	1	2	1	3	4	01/27/98	Hadlaczky	435	172.2	01/19/95
*	N	5	7	2	1	1	1	8	02/24/98	Scheffler	435	69.1	10/29/96
*	O	5	7	3	6	3	9	2	04/07/98	Hawley-Nelson <i>et al.</i>	435	320.1	06/04/96
	P	5	7	4	7	0	7	2	05/05/98	Davidson <i>et al.</i>	424	93.2	04/14/95
*	Q	5	8	3	0	4	3	0	11/03/98	Unger <i>et al.</i>	424	1.21	02/21/95
*	R	5	8	4	3	8	8	4	12/01/98	Sims	514	2	11/15/95
*	S	5	8	5	3	6	9	4	12/29/98	Engberts <i>et al.</i>	424	1.21	07/24/96
*	T	5	8	6	9	2	9	4	02/09/99	Harrington <i>et al.</i>	435	91.1	09/20/96
*	U	5	8	9	1	6	9	1	04/06/99	Hadlaczky	435	172.3	10/21/96
*	V	5	9	4	4	7	1	0	08/31/99	Dev <i>et al.</i>	604	500	06/24/96
*	W	5	9	6	2	2	6	5	10/05/99	Norris <i>et al.</i>	435	69.1	12/15/98

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Title: **METHODS FOR DELIVERING NUCLEIC ACID MOLECULES INTO CELLS AND ASSESSMENT THEREOF**

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EXAMINER INITIAL	Ref. No.	DOCUMENT NUMBER							DATE	NAME	CLASS	SUB CLASS	FILING DATE
*	X	5	9	6	5	3	9	6	10/12/99	Pan <i>et al.</i>	435	69.1	01/13/98
*	Y	5	9	7	6	7	9	6	11/02/99	Szalay <i>et al.</i>	435	6	12/23/96
*	Z	5	9	7	6	8	4	9	11/02/99	Hustad <i>et al.</i>	435	183	04/30/98
*	AA	5	9	8	5	5	7	7	11/16/99	Bulinski	435	6	10/14/98
*	AB	5	9	9	3	4	3	4	11/30/99	Dev <i>et al.</i>	604	501	09/29/95
*	AC	6	0	2	5	1	5	5	02/15/00	Hadlaczky <i>et al.</i>	435	69.1	08/07/96
*	AD	6	0	2	7	4	8	8	02/22/00	Hofmann <i>et al.</i>	604	522	06/03/98
*	AE	6	0	3	4	2	2	8	03/07/00	Norris <i>et al.</i>	536	23.1	06/25/99
*	AF	6	0	3	7	1	3	3	03/14/00	Li	435	7.21	04/17/98
	AG	6	0	5	1	4	2	9	04/18/00	Hawley-Nelson <i>et al.</i>	435	458	03/14/97
*	AH	6	0	5	4	3	1	2	04/25/00	Larocca <i>et al.</i>	435	320.1	08/29/97
*	AI	6	0	7	4	6	6	7	06/13/00	Kinnunen <i>et al.</i>	424	450	05/21/98
*	AJ	6	0	7	7	6	9	7	06/20/00	Hadlaczky <i>et al.</i>	435	172.3	07/15/96
*	AK	6	1	8	4	0	3	7	02/06/01	Rolland <i>et al.</i>	435	455	05/02/97

FOREIGN PATENT DOCUMENTS

	*Ref No.	DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUB CLASS	Translation Yes No	
	AL	0	0	2	7	7	9	5	05/18/00	PCT				
	AM	0	0	5	2	1	8	6	09/08/00	PCT				
*	AN	0	7	5	5	9	2	4	01/29/97	EP A1				
*	AO	0	7	5	5	9	2	4	06/09/99	EP B1				
*	AP	9	7	4	0	1	8	3	10/30/97	PCT				
*	AQ	9	8	0	8	9	6	4	03/05/98	PCT				
*	AR	9	9	2	1	5	8	4	05/06/99	PCT				

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## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

*	AS	1999 Press Releases: "Chromos Molecular Systems Demonstrates Large-Scale Isolation of Mammalian Artificial Chromosomes"; <a href="http://www.chromos.com/feb399.htm1">http://www.chromos.com/feb399.htm1</a>
*	AT	1999 Press Releases: "Chromos Molecular Systems Reports <i>In Vitro</i> and <i>In Vivo</i> Stability of Functional Mammalian Artificial Chromosome"; <a href="http://www.chromos.com/march1899.htm1">http://www.chromos.com/march1899.htm1</a>
*	AU	2001 Press Releases: "Chromos Presents New Chromosome-Based Platform Technology for Gene Therapy (ASGT)"; <a href="http://www.chromos.com/June%204.htm1">http://www.chromos.com/June%204.htm1</a>
*	AV	2001 Press Releases: "Chromos Announces Publication of Rapid Screening Technique in the Journal Cytometry"; <a href="http://www.chromos.com/June%207.htm1">http://www.chromos.com/June%207.htm1</a>
*	AW	2001 Press Releases: "Chromos Initates Research into Plant Artificial Chromosomes"; <a href="http://www.chromos.com/Jan23.htm1">http://www.chromos.com/Jan23.htm1</a>
*	AX	2001 Press Releases: "Chromos Announces Expression of Therapeutic Protein in Transgenic Animal Carrying an Artificial Chromosome"; <a href="http://www.chromos.com/nov8.htm1">http://www.chromos.com/nov8.htm1</a>
*	AY	2001 Press Releases: "Chromos Reports Data on Transgenic Animals Carrying Artificial Chromosome"; <a href="http://www.chromos.com/march28.htm1">http://www.chromos.com/march28.htm1</a>
*	AZ	2001 Press Releases: "Chromos and Biological Research Center Announce Publication of Human Artificial Chromosome Methodology in the Journal of Cell Science"; <a href="http://www.chromos.com/sept12.htm1">http://www.chromos.com/sept12.htm1</a>
	BA	2002 Press Release: "Chromos Announces Agreement With Lonza Biologics PLC: ACE System to be Evaluated by Leading Contract Protein Manufacturer" Burnaby, BC, Canada, <a href="http://www.chromos.com/june10.html">http://www.chromos.com/june10.html</a> (09/12/02)
	BB	2002 Press Release: "Chromos Reports Progress In Gene Delivery To Adult Derived Stem Cells" Burnaby, BC, Canada, <a href="http://www.chromos.com/june6.html">http://www.chromos.com/june6.html</a> (09/12/02)
	BC	2002 Press Release: "Chromos Enters Collaboration Agreement with Morphogen Pharmaceuticals" Burnaby, BC, Canada, <a href="http://www.chromos.com/april24.html">http://www.chromos.com/april24.html</a> (09/12/02)
*	BD	Alton <i>et al.</i> , "Nucleotide sequence analysis of the chloramphenicol resistance transposon Tn9", <i>Nature</i> , <u>282</u> :864-869 (1979)
	BE	Alvaro-Gracia <i>et al.</i> , "Cytokines in Chronic Inflammatory Arthritis. V. Mutual Antagonism between Interferon-Gamma and Tumor Necrosis Factor-Alpha on HLA-DR Expression, Proliferation, Collagenase Production, and Granulocyte Macrophage Colony-stimulating Factor Production by Rheumatoid Arthritis Synoviocytes", <u>86</u> :1790-1798 (1990)

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*	BF	Anderson <i>et al.</i> , "Flow Cytometry of Mitotic Cells", <i>Experimental Cell Res.</i> , <u>238</u> :498-502 (1998)
	BG	ATCC (American Type Culture Collection) Number CCL-39
	BH	ATCC (American Type Culture Collection) Number CCL-1.3
	BI	ATCC (American Type Culture Collection) Number CCL-110
	BJ	ATCC (American Type Culture Collection) Number CRL-1573
	BK	ATCC (American Type Culture Collection) Number CCL-1.4
	BL	ATCC (American Type Culture Collection) Number CRL-2056
	BM	ATCC (American Type Culture Collection) Number CRL-1769
*	BN	Audouy <i>et al.</i> , "Serum as a modulator of lipoplex-mediated gene transfection: dependence of amphiphile, cell type and complex stability", <i>J. Gene Med.</i> , <u>2</u> :465-476 (2000)
	BO	Audouy and Hoekstra, "Cationic lipid-mediated transfection <i>in vitro</i> and <i>in vivo</i> (Review)", <i>Molecular Membrane Biology</i> , <u>18</u> :129-143 (2001)
	BP	Aupperle <i>et al.</i> , "NF- $\kappa$ B Regulation by I $\kappa$ B Kinase in Primary Fibroblast-Like Synoviocytes", <i>The Journal of Immunology</i> , <u>163</u> :427-433 (1999)
*	BQ	Baldwin <i>et al.</i> , "Cloning of the Luciferase Structural Genes from <i>Vibrio harveyi</i> and Expression of Bioluminescence in <i>Escherichia coli</i> ", <i>Biochem.</i> , <u>23</u> :3663-3667 (1984)
*	BR	Bao <i>et al.</i> , "Transfection Of A Reporter Plasmid Into Cultured Cells By Sonoporation <i>In Vitro</i> ", <i>Ultrasound in Med. &amp; Biol.</i> , <u>23/6</u> :953-959 (1997)
*	BS	Basic Protocol, Book: <u>Current Protocols in Molecular Biology</u> , Supplement 14, "Calcium Phosphate Transfection", Section 1, Unit 9.1.1 - 9.1.9 (1990)
	BT	Bendele <i>et al.</i> , "Efficacy of Sustained Blood Levels of Interleukin-1 Receptor Antagonist in Animal Models of Arthritis", <i>Arthritis and Rheumatism</i> , <u>42(3)</u> :498-506 (1999)
*	BU	Caldwell <i>et al.</i> "Activation of Genes with Ultrasound," <i>Ultrasound Contrast Research Symposium</i> San Diego, CA February 6-8, 1998
*	BV	Co <i>et al.</i> , "Generation of transgenic mice and germline transmission of a mammalian artificial chromosome introduced into embryos by pronuclear microinjection", <i>Chromosome Res.</i> , <u>8</u> :183-191 (2000)

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## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	BW	Corrigall <i>et al.</i> , "Functional IL-2 Receptor $\beta$ (CD122) and $\gamma$ (CD132) Chains Are Expressed by Fibroblast-Like Synoviocytes: Activation by IL-2 Stimulates Monocyte Chemoattractant Protein-1 Production", <i>The Journal of Immunology</i> , <u>166</u> :4141-4147 (2001)
*	BX	Csonka <i>et al.</i> , "Novel generation of human satellite DNA-based artificial chromosomes in mammalian cells", <i>J. of Cell Sci.</i> , <u>113</u> :3207-3216 (2000)
*	BY	de Wet <i>et al.</i> , "Firefly Luciferase Gene: Structure and Expression in Mammalian Cells", <i>Molecular and Cellular Biol.</i> , <u>7/2</u> :725-737 (1987)
	BZ	de Jong <i>et al.</i> , "Efficient <i>in-vitro</i> transfer of a 60-Mb mammalian artificial chromosome into murine and hamster cells using cationic lipids and dendrimers," <i>Chromosome Res.</i> , <u>9(6)</u> :475-485 (2001)
*	CA	de Jong <i>et al.</i> , "Mammalian Artificial Chromosome Pilot Production Facility: Large-Scale Isolation of Functional Satellite DNA-Based Artificial Chromosomes", <i>Cytometry</i> , <u>35</u> :129-133 (1999)
*	CB	de Jong <i>et al.</i> , Abstract No. 550: "In Vitro Transfer of a 60 Mb Mammalian Artificial Chromosome into Primary Cell Lines Using Cationic Lipids an a Dendrimer", one page
*	CC	de Jonge <i>et al.</i> , "Chromosome and DNA-Mediated Gene Transfer in Cultured Mammalian Cells", <i>International Review of Cytology</i> , <u>92</u> :133-158 (1984)
	CD	Del Vecchio <i>et al.</i> , "Approaches to enhancing the retroviral transduction of human synoviocytes", <i>Arthritis Research</i> , <u>3</u> :259-263 (2001)
*	CE	Durand <i>et al.</i> , "Sequencing Radiation and Adriamycin Exposures in Spheroids to Maximize Therapeutic Gain", <i>I. J. Radiation Oncol. Biol. Phys.</i> , <u>17/2</u> :345-350 (1989)
*	CF	Durand <i>et al.</i> , "Response of Cell Subpopulations in Spheroids to Radiation-Drug Combinations", <i>NCI Monogr.</i> , <u>6</u> :95-100 (1988)
*	CG	Durand <i>et al.</i> , "Schedule Dependence for Cisplatin and Etoposide Multifraction Treatments of Spheroids", <i>J. Natl. Cancer Inst.</i> , <u>82/23</u> :1841-1845 (1990)
	CH	ECACC (European Collection of Cell Cultures) No: 85110503, Cell Line Name: NS0, mouse myeloma
	CI	Edwards, J.C.W., "Fibroblast biology: Development and differentiation of synovial fibroblasts in arthritis", <i>Arthritis Research</i> , <u>2(5)</u> :344-347 (2000)
	CJ	Edwards, J.C.W. "Synovial intimal fibroblasts," <i>Ann. Rheum. Dis.</i> , <u>54</u> :395-397 (1995)

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## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

*	CK	Engbrecht <i>et al.</i> , "Identification of genes and gene products necessary for bacterial bioluminescence", <i>Proc. Natl. Acad. Sci. USA</i> , <u>81</u> :4154-4158 (1984)
	CL	Evans <i>et al.</i> , "Clinical Trial to Assess the Safety, Feasibility, and Efficacy of Transferring a Potentially Anti-Arthritic Cytokine Gene to Human Joints with Rheumatoid Arthritis," <i>Human Gen. Ther.</i> , <u>7</u> :1261-1280 (1996)
	CM	Firestein, G.S., "Invasive Fibroblast-Like Synoviocytes in Rheumatoid Arthritis," <i>Arthritis Rheum.</i> , <u>39</u> :1781-1790 (1996)
*	CN	Fritz <i>et al.</i> , Abstract: "Ultrasound Enhancement of Gene Expression, Newly Discovered Cationic Lipids, and a New Class of Gene Delivery Agents", ImaRx Pharmaceutical Corp. Announces Important Discoveries in Emerging Field of Drug Delivery Using Acoustically Active Carriers, <i>ImaRx Pharmaceutical Corp.</i> , pages 1-2 (2001)
	CO	Gerlag <i>et al.</i> , "The Effect of a T Cell-Specific NF- $\kappa$ B Inhibitor on In vitro Cytokine Production and Collagen-Induced Arthritis," <i>J. Immunol.</i> , <u>165</u> :1652-1658 (2000)
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